IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel.* ZACHARY SILBERSHER, *Plaintiffs*, vs. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and JOHNSON & JOHNSON, *Defendants*.	Civil Action No. 19-12107 (MEF) (SDA) *Document electronically filed*

BRIEF OF RELATOR ZACHARY SILBERSHER OBJECTING TO SPECIAL MASTER ORDER DENYING MOTION FOR *IN CAMERA* REVIEW OF DOCUMENTS PURSUANT TO THE CRIME-FRAUD EXCEPTION

LITE DEPALMA GREENBERG & AFANADOR, LLC
Bruce D. Greenberg
570 Broad Street, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
Fax: (973) 623-0858
bgreenberg@litedepalma.com

Attorneys for Plaintiff-Relator Zachary Silbersher
[Additional Counsel on Signature Page]

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INTRODUCTION AND OVERVIEW

Relator Zachary Silbersher respectfully submits this memorandum (i) objecting to the Special Master Order filed October 4, 2024 (ECF No. 374) ("Order") denying Relator's Motion for *In Camera Review* (Moving Brief ("Br."), ECF No. 346)[1]; and (ii) renewing Relator's Motion.

Relator asks this Court, in exercising *de novo* review of the Order pursuant to Fed. R. Civ. P. 53(f)(3), (4), to require Defendants to submit to the Court for *in camera* review certain documents redacted or withheld from production based on the attorney-client privilege or work product doctrine. Defendants have redacted or withheld over 2,400 documents on the basis of privilege, and they have refused to provide greater detail in their privilege log to enable more focused identification of potential documents for review. Nevertheless, Relator has narrowed the target date range to a period during which he believes the highest concentration of crime-fraud communications exist, and he has further focused the list to an initial set of 200 of the most promising documents for *in camera* review, with the 50 most important highlighted. *See* Declaration of Bruce D. Greenberg dated October 25, 2024 ("Greenberg Decl. III"), at Ex. 30.[2]

Relator alleges in his operative second amended complaint (ECF No. 63) (the "Complaint" or "SAC") that Defendants caused the United States and Plaintiff States (collectively, the "Government") to pay hundreds of millions of dollars more for Defendants' prostate cancer drug,

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[1] Relator's Notice of Motion is filed as ECF No. 345. A sealed, unredacted version of Relator's Reply is filed as ECF No. 363.

Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson ("Defendants") filed a sealed, unredacted Opposition Brief ("Opp.") at ECF No. 355. Defendants filed a supporting Declaration of Jeffrey Greenbaum (Greenbaum Decl.) as ECF No. 354-1.

[2] The exhibits to the Greenberg Declaration III combine exhibits 1 through 32 of Greenberg Declarations I and II in the order they appeared in those declarations, but with some lengthy documents reduced to excerpts. The only additional documents added here are Exhibits 33 through 35. Citations to exhibits in the Greenberg Declaration III are hereafter cited as "Ex.__."

Zytiga (abiraterone acetate), than they should have. The Government overpaid monopoly prices because Defendants unlawfully obtained a fraudulent patent on Zytiga that they then listed in the FDA's Orange Book (to trigger a regulatory stay of generic approval) and then asserted in patent litigation to exclude generic entry. As a result, Medicare and other payors paid in some cases almost $10,000 per monthly prescription for Zytiga during the unlawful monopoly period; but now that the fraudulent patent has been invalidated, the price for generic Zytiga has plummeted to as low as a few hundred dollars. The gist of the Complaint therefore is this: When a drug company obtains a patent through fraud and then asserts the fraudulent patent against generic competitors through regulatory and legal proceedings to keep them off the market, then every single claim made to Government programs for the drug (such as Medicare or Medicaid reimbursements, or direct purchase by the Veterans' Health Administration for disbursement at VA hospitals) is a false claim under the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA"), and state FCA analogues.

This case was originally assigned to the Hon. Kevin McNulty, who denied Defendants' motion to dismiss. In a thorough and well-reasoned decision, this Court held that Relator's theories of fraud were valid, and the Complaint's allegations sufficiently pleaded that Defendants' representations to the U.S. Patent and Trademark Office in obtaining the subject patent, U.S. Patent 8,822,438 ("the '438 patent"), were fraudulent. *United States v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212, 228 (D.N.J. 2021), *motion to certify appeal denied*, 2022 WL 225475 (Jan. 26, 2022).

The crime-fraud exception exists precisely for situations like this, where schemes are planned, approved, and deployed through the advice and actions of in-house patent and litigation counsel. *Cf. In re Abbott Labs.*, 96 F.4th 371 (3d Cir. 2024) (holding that crime-fraud exception applied to communications by pharmaceutical manufacturer's "in-house counsel concerning whether to file" a baseless patent infringement lawsuit for the purpose of improperly preventing

generic competition). The advice and analysis of Defendants' in-house patent and litigation counsel were an integral part of the necessary planning and implementation of Defendants' complex fraudulent scheme to block generic competition, thus unlawfully preserving Defendants' monopoly market share and profits.

Based on the nature of redacted documents produced by Defendants in discovery, and the descriptions of withheld documents in Defendants' privilege logs, Relator believes the documents he seeks to be reviewed *in camera* may reflect actions and communications in furtherance of Defendants' fraudulent scheme. The fraudulent scheme was complex. It required not only obtaining the patent, but also wielding it effectively against competitors. Doing so required manipulating complex administrative and legal regulations and proceedings to maximize not only the delay to generic competition, but also the monopoly profits that Defendants could extract during that time (mostly from Government payors). In-house patent counsel's communications with executives and managers were necessarily at the heart of those efforts. And of course, counsel played a central role in implementing the fraud by making the regulatory and legal filings.

The standard for *in camera* review is a lenient one. Relator needs only to make a showing of "a factual basis adequate to support a good faith belief by a reasonable person that *in camera* review of the materials may reveal evidence to establish the claim that the crime-fraud exception applies." *United States v. Zolin*, 491 U.S. 554, 572 (1989). This standard is intended to be even more lenient than a *prima facie* showing. Defendants' alibis are beside the point. Relator established the necessary factual basis by citing ample evidence in support of his allegations, as detailed below. Of course, Defendants can be expected to offer their alibis in rebuttal, but that does not render Relator's factual showing inadequate to support a good faith belief justifying *in camera* review. That just means there is a dispute of fact that can be resolved later by a jury. The

fundamental error in the Special Master Order is that it resolved factual disputes in Defendants' favor and accepted Defendants' alibis wholesale without an adequate record. This is inconsistent with how courts should assess the application of the *in camera* review doctrine. And it cuts against the entire purpose of *in camera* review, during which the Court can make a determination whether the crime-fraud doctrine applies, *i.e.*, whether the communications in fact furthered fraud.

This motion is directed only to the specific time period between July 3, 2013 (when Defendants received the first Notice of Allowance for the '438 Patent, putting them on notice that the Patent Office intended to grant the patent based solely on their fraudulent submission regarding commercial success) and September 30, 2014 (when Defendants listed the '438 Patent in the Orange Book, by which time they committed to unlawfully wielding the patent against their competitors). The Court should conduct an *in camera* review of documents within this time period.

FACTUAL, PROCEDURAL, AND LEGAL BACKGROUND

The following statement of facts is substantially based on the Relator's Brief on the original motion (ECF No. 346) and only cites documents originally submitted to the Special Master, except for Ex. 35 in footnote 6, which is the transcript of the oral argument before the Special Master.

A. Defendants Make a Fraudulent Submission to the Patent Office and Receive a Notice of Allowance Based Solely on Their Commercial Success Argument

The way the fraud worked is this. Zytiga was originally covered by a chemical compound patent on Zytiga's active pharmaceutical ingredient, abiraterone acetate (often referred to as the '213 patent), which expired in December 2016. As the '213 patent drew close to its expiration, Defendants attempted to extend their patent monopoly for Zytiga by applying for a method of use patent claiming as inventive the coadministration of Zytiga with prednisone (which the FDA required because of observed side effects from taking abiraterone without a concomitant corticosteroid). The Patent Office rejected the application multiple times because the claimed

invention (administering Zytiga with prednisone) was obvious based on what was known at the time. After many failed attempts, the patent application was finally allowed after Defendants made misrepresentations and omissions of material fact about Zytiga's purported commercial success.

In short, Defendants misrepresented that prednisone coadministration purportedly caused Zytiga to achieve commercial success against competitors, supposedly proving that prednisone coadministration must not have been obvious at the time, because an efficient market would have been expected to exploit such an invention earlier. Under patent law, this is known as a "secondary consideration" that overcomes an objection that the patent claims were obvious.[3] Defendants' statements to the Patent Office were fraudulent, because Zytiga was an effective treatment that was successful *in spite of*—not *because of*—the need to administer the drug with prednisone. Defendants knew this, or at least were reckless or deliberately ignorant to the truth. Had Defendants been honest, the '438 Patent would never have been granted.

It is critical to note that the '438 Patent has been invalidated, and Defendants' commercial success argument rejected, at least five times now: Three separate times by the Patent Office's Patent Trial and Appeal Board ("PTAB"); once by this Court; and once by the Federal Circuit. *See Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, No. IPR2016-00286, 2018 WL 454509, at *18 (P.T.A.B. Jan. 17, 2018); *Mylan Pharms. Inc. v. Janssen Oncology, Inc.,* No. IPR2016-01332,

[3] A patent may be granted despite an obviousness objection if the claimed invention exhibits certain commercial success. "Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). Yet, for evidence of commercial success to overcome a *prima facie* case of obviousness, "[a] nexus between commercial success and the claimed features is required." *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000). "[T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art." *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997).

2018 WL 456305, at *18 (P.T.A.B. Jan. 17, 2018); *Wockhardt Bio Ag v. Janssen Oncology, Inc.,* No. IPR2016-01582, 2018 WL 456328, at *21 (P.T.A.B. Jan. 17, 2018); *BTG Int'l Ltd. v. Amneal Pharms LLC*, 352 F. Supp. 3d 352, 386 (D.N.J. 2018) (McNulty, J.); *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063, 1076 (Fed. Cir. 2019). Indeed, if Defendants' commercial success argument—including Defendants' contentions that prednisone coadministration somehow increased the efficacy of Zytiga—had any merit, the PTAB and the courts could not have concluded that the patent was invalid. Therefore, the only real question for liability is whether, besides being meritless, Defendants' commercial success argument was fraudulent (*i.e.*, knowingly false, deliberately ignorant, or reckless). This is a scienter issue for the jury.

On June 4, 2013, Defendants made their key submission to the Patent Office regarding their commercial success argument (the "June 2013 Submission"). (Ex. 2.) Defendants represented that the claimed "invention [*i.e.*, prednisone coadministration] has displayed commercial success." (*Id.* at 6.) Defendants' internal documents demonstrate they knew there was no nexus between Zytiga's commercial success and the claimed invention. In fact, those documents prove Defendants believed the opposite. Numerous documents show that executives and managers at the highest levels believed prednisone coadministration was a principal ***weakness*** with respect to Zytiga's commercial success, not a strength that was responsible for driving it.

For example, a Global Brand Book distributed by Defendants' Global Strategic Marketing Team in early 2011 [redacted]

Outside of marketing, Defendants' analyses in many other financial, operational, medical, and executive presentations confirmed that their patent attorneys, executives, managers, and

scientists understood prednisone coadministration to be significant weakness that presented a major threat to Zytiga's commercial success, contrary to what the Defendants told the Patent Office. For example, a [redacted]

Many independent industry analysts agreed, and [redacted]

[redacted]

Influential members of the medical community also considered prednisone coadministration a significant competitive weakness, and they repeatedly told Defendants about it. For example, [redacted] They confirmed that, far from considering prednisone coadministration a competitive strength of Zytiga, the medical community viewed it as a major weakness. (*See, e.g.*, *id.* at 47.)

Moreover, on March 14, 2013, [redacted] Prescribing doctors were right to be wary because of the well-known side effects of chronic prednisone use, such as increased risk of infection, arrythmias, and other serious adverse effects.[4]

Even one of the supposed "inventors" of the '438 Patent, [redacted]

[4] *See, e.g.*, https://www.ncbi.nlm.nih.gov/books/NBK531462/.

[redacted] (Ex. 9.)

Together, these and many other documents demonstrate that Defendants knew prednisone was a major "weakness" threatening Zytiga's commercial success, and certainly not a reason for it. Therefore, Defendants made a knowingly false statement when they told the Patent Office that the invention claimed in the '438 Patent was responsible for its commercial success. This false submission was the *sole* reason that the Patent Office reversed its prior rejections and instead granted the '438 Patent. (Ex. 12, at p. 85 of 329)[5]

Defendants went even further by knowingly omitting from their June 2013 Submission the *actual* reasons for Zytiga's commercial success, which they were obligated affirmatively to disclose because their duty of candor and good faith required them to do so. 37 C.F.R. § 1.56 (pre-AIA) (patent applicants have "duty of candor and good faith," which includes a duty to disclose *all* information "material to patentability"). For example, Defendants had an exclusive license to the '213 patent covering abiraterone acetate, the chemical compound for Zytiga. That exclusive license prevented any other company from making, using, or selling the drug. And just as importantly, the exclusive license would have prevented other companies from investigating prednisone coadministration and commercializing the concept—which undermines the entire rationale for the commercial success argument that Defendants submitted to the Patent Office.

Although the '438 Patent discloses and refers to the '213 Patent, Defendants failed to disclose when making the commercial success argument (as they were required to do under their duty of candor) that Defendants were exclusive licensees of the '213 Patent, which was a blocking

[5] Because of multiple documents in the exhibit, the pinpoint citation refers to the page number of the PDF containing the exhibit. Citations for similar group or lengthy exhibits are used herein.

patent.[6] As determined by both the PTAB and this Court, Defendants' exclusive license to a blocking patent was a primary reason for Zytiga's commercial success. This Court held: "The existence of a blocking patent [from] 1997 through 2006 (indeed, through 2016), despite some desultory licensing efforts, would have discouraged entry at the very time when the obviousness of combination therapy was manifesting itself." *BTG*, 352 F. Supp. 3d at 387. Similarly, the PTAB found "the commercial success of Zytiga is mitigated by the existence of a blocking patent. . . . [T]he blocking patent would have deterred others from exploring the commercial potential of abiraterone acetate, and thus, that blocking patent to abiraterone acetate limits the applicability of other evidence of commercial success." *Wockhardt*, 2018 WL 456328, at *43.

Defendants also concealed from the Patent Office other major factors they knew were the real drivers of Zytiga's commercial success, but which were unrelated to the invention claimed in the '438 Patent. These included, *inter alia*, the efficacy of abiraterone acetate as a new treatment compared with legacy treatments and Zytiga's first mover advantage against emerging competing treatments, such as Xtandi, which had not yet obtained FDA approval. [redacted]

[6] Defendants denied this allegation in their opposition, offering Greenbaum Decl. Ex. I as proof that they disclosed an exclusive license to the Patent Office. [redacted] These purported disclosures simply do not satisfy Defendants' duty of candor and good faith, which required Defendants to explain—as found by the district court and the PTAB—that Defendants *exclusive* license created a blocking patent that directly undermined the commercial success argument. *See* M.P.E.P. § 2001.04.

supra n.7). Those primary commercial strengths were recognized by Defendants' leadership and in-house attorneys, but Defendants chose not to disclose them. (*See, e.g.*, Ex. 7 at 33, 44, 47.)

As one example of the importance of these undisclosed factors to Zytiga's commercial success, Defendants knew [redacted] As early as March 2010, Defendants [redacted] The chemical compound responsible for Zytiga's efficacy is covered by the earlier '213 blocking patent. Thus, abiraterone acetate, which is the effective chemical compound of Zytiga, is in the prior art, and was the primary reason for Zytiga's commercial success. This invalidates Defendants' commercial success argument and should have been disclosed to the Patent Office. *See Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011) ("If commercial success is due to an element in the prior art, no nexus exists."). Zytiga's commercial success lacked any nexus to prednisone coadministration, and Defendants knew it.

Relator has therefore provided ample evidence establishing a factual basis for Relator's contention that Defendants' pivotal June 2013 Submission to the Patent Office regarding their commercial success argument was not just wrong—it was fraudulent. On July 3, 2013, after having repeatedly rejected Defendants' application for the '438 Patent as obvious based on the prior art, the Patent Office issued a Notice of Allowance based solely on Defendants' fraudulent commercial success argument. (SAC ¶ 85; Ex. 12 at 7 (July 3, 2013 Notice of Allowance).)

B. Defendants Continued to Prosecute the '438 Patent and Requested That It Be Issued Without Correcting Any of Their Misrepresentations or Omissions, and Despite Believing It Would Have Been Promptly Invalidated

News of the July 3, 2013 Notice of Allowance for the '438 Patent was disseminated in industry analyst reports, prompting a flurry of discussion within Defendants' senior leadership.

Several documents from the time are highly redacted, so it is difficult to discern the exact context, but the unredacted portions [redacted]

Further discussions followed rapidly as additional analyst reports came out. For example, [redacted]

Soon after this, another of Defendants' in-house patent attorneys—Timothy Tracy—took over primary responsibility. (Ex. 16 (Kamage Tr.) at 243:6-21; Ex. 17 (Tracy Tr.) at 177:4-21.) Defendants, with Mr. Tracy now responsible for the patent prosecution, had a choice to make. The Patent Office had consistently rejected all of Defendants' attempts to show that the claimed invention in the '438 Patent was nonobvious in light of the prior art. The only basis on which the Patent Office agreed to allow the patent was the fraudulent commercial success argument. Defendants could correct the record by informing the Patent Office that, in fact, Defendants

considered coadministration with prednisone a weakness of Zytiga, rather than a strength. They could also disclose the true reasons for Zytiga's commercial success, including their exclusive license to the '213 blocking patent. Or Defendants could continue to prosecute the patent under the false pretense that the patent should be granted based on commercial success. Defendants chose the latter, and communications concerning that decision likely furthered the fraudulent scheme.

Mr. Tracy engaged in a pattern of repeatedly requesting continued examination of the patent and submitting piecemeal information in disclosure statements attaching additional prior art—but nothing to correct the misleading statements and omissions relating to the commercial success submission. (*See generally* Ex. 19.) Each time, the Patent Office responded in the same way: the patent was being allowed, not because of anything having to do with prior art, but instead based on the same reason as before—the purported commercial success of Zytiga. (*Ibid.*) Defendants' privilege logs show that, throughout this process, Mr. Tracy was providing advice to Defendants regarding the "Zytiga patents," i.e., the '213 Patent and '438 Patent, as well as advice regarding the marketing of Zytiga. Those emails are also likely in furtherance of the fraud, particularly if Mr. Tracy determined not to correct the June 2013 Submission.

In the meantime, Defendants needed to assess the impact that issuance of the '438 Patent would have on their projected loss of exclusivity (LOE) date for Zytiga, which is an extraordinarily important projection setting Defendants' operational planning and budgetary and resource allocation decisions. Prior to the July 2013 Notice of Allowance, Defendants had consistently [redacted] Defendants never projected that [redacted]

[redacted]

In January 2014, Defendants [redacted] Defendants were keenly aware that once the '438 Patent was issued, it would—at least on its face—confer exclusivity on Zytiga for over 10 years beyond the expiration of the '213 Patent. Zytiga was generating revenue for Defendants of hundreds of millions of dollars annually, and an additional decade-plus of exclusivity would have made a significant impact. It was therefore imperative that Defendants appropriately determine, for financial planning and resource allocation purposes, the period of exclusivity that the '438 Patent would provide.

The results of Defendants' analysis are telling. As of early March 2014 (eight months after Defendants received the July 2013 Notice of Allowance for their patent application), Defendants' [redacted] By March 26, 2014, however, Defendants' [redacted]

Two days later, [redacted]

[redacted]

Defendants continued [redacted]

[redacted] (For reference, the PTAB later invalidated '438 Patent in January 2018, and this Court's decision was filed on October 31, 2018—consistent with Defendants' [redacted].)

Clearly, with this much at stake financially, it was important for Defendants to have the best possible projection as to the most likely scenario for when the '438 Patent would be invalidated. Paul Short, the commercial leader for Zytiga, testified that [redacted]

[redacted] (Ex. 18 (Short Tr.) at 283:15-19; 287:13-288:3.) Yet when the patent attorney overseeing the '438 Patent at this time (Timothy Tracy) was asked [redacted], Mr. Tracy was evasive. He [redacted] (Ex. 17 (Tracy Tr.) at 314:6-315:2; 333:15-337:8.) Mr. Tracy [redacted]

It strains credulity to suggest that, with hundreds of millions of dollars of annual revenue on the line, Defendants would [redacted] without requesting the advice of their in-house patent counsel. And Mr. Tracy's testimony is contradicted by the fact that in February 2014, [redacted], he received a [redacted]

Defendants' contemporaneous internal projections as to the likely invalidation of the '438 Patent are significant. Defendants knew they had obtained the Notice of Allowance through misrepresentations and omissions regarding commercial success, and that none of their other arguments in favor of patentability had received any traction at the Patent Office. Defendants must have expected generic drugmakers to challenge the '438 Patent by filing Abbreviated New Drug

Applications (ANDA) soon after they were first permitted, which they did: ANDA filings for Zytiga could be filed as early as April 2015, and the vast majority of the ANDA filers did so in June and July 2015. (*See* SAC ¶ 95.) Defendants also knew that if they responded to those ANDA filings by initiating patent infringement actions, they would trigger the automatic 30-month stay under the Hatch-Waxman Act, which would expire in October 2018. Defendants therefore understood that the only way they would lose the exclusivity conferred by the '438 Patent prior to October 2018 would be if a court invalidated the patent (or found that it was not infringed) sooner. Accordingly, Defendants' counsel therefore must have estimated it would take two years until a court would invalidate the '438 Patent. This was Defendants' actual belief, as reported to their senior leadership [redacted]

This is highly probative of Defendants' culpable knowledge during the very time when they continued to act in furtherance of their fraud by continuing to prosecute the '438 Patent.

Defendants ultimately decided, despite apparently lacking a good faith belief that the '438 Patent could withstand a validity challenge, to go ahead and have the patent issued anyway. On July 28, 2014, Defendants, through Mr. Tracy, transmitted the issuance fee to the Patent Office. (Ex. 26.) In response, on September 2, 2014, the Patent Office issued the '438 Patent. (Ex. 27.)

Defendants' fraudulent scheme did not stop there. They were next faced with the decision whether to list their fraudulently obtained patent in the FDA's Orange Book. This required Defendants to have a good faith belief they could assert a claim of infringement of the '438 Patent against a generic competitor. *See* 21 C.F.R. 314.53(b). This in turn required Defendants to have a good faith belief the patent was valid. Yet on September 16, 2014, just two weeks before Defendants, through Mr. Tracy, listed the patent in the Orange Book (Ex. 29)—Defendants gave

a [redacted] Thus, the highest-level governance body in Defendants' pharmaceuticals business maintained that [redacted] a belief fundamentally incompatible with a good faith belief in the validity of the '438 Patent. (*Id.*)

Counsel's communications analyzing whether to have the patent issued by the Patent Office, determining whether to list it in the Orange Book, and providing estimates of when the PTAB and the Court would invalidate the '438 Patent [redacted] would likely have been in furtherance of the fraud—in addition to being direct evidence of the fraud itself. And of course, their research and analysis of the risks of having the patent issued or listed in the Orange Book would have been in furtherance of their eventual *actions* implementing the fraud through counsel's regulatory and legal filings. *See Abbott*, 96 F.4th at 377-78.

C. Defendants Redact and Withhold Hundreds of Documents That Appear to Reflect Actions and Communications in Furtherance of their Fraudulent Prosecution of the '438 Patent and Fraudulent Listing in the Orange Book

Defendants have produced two primary privilege logs in this litigation—dated July 14, 2023 and September 12, 2023—that contain a total of over 2,400 entries. Many of the entries appear, based on their dates and descriptions, to reflect attorney-client communications and work product in furtherance of Defendants' fraudulent prosecution of the '438 Patent and subsequent

fraudulent listing in the Orange Book. A number of partially redacted documents—improperly omitted from the privilege logs—appear to do so as well.

Relator has identified a subset likely containing a high concentration of crime-fraud documents from July 3, 2013 to September 30, 2014. A list of approximately 200 of these documents is set forth in Exhibit 30, with 50 of the highest priority highlighted should the Court prefer to initially review a smaller batch to confirm the existence of crime-fraud communications.

ARGUMENT

I. Standard of Review

The Court should review the Special Master Order's findings of fact and legal conclusions *de novo.* Fed. R. Civ. P. 53(f)(3), (4).

Under the crime-fraud exception, communications made between an attorney and client in furtherance of future wrongdoing are not protected by the privilege. *In re Grand Jury*, 705 F.3d 133, 151 (3d Cir. 2012) (citing *United States v. Zolin*, 491 U.S. 554, 562-63 (1989)). A party seeking to invoke the crime-fraud exception to overcome the privilege "must make a *prima facie* showing that (1) the client was committing or intending to commit a fraud or crime, and (2) the attorney-client communications were in furtherance of that alleged crime or fraud." *Id.* "All that is necessary is that the client misuse or intend to misuse the attorney's advice in furtherance of an *improper purpose*. When this occurs, the purpose of the privilege, to promote the fair administration of justice, has been undermined and the privilege no longer applies." *In re Abbott Labs.*, 96 F.4th 371, 381 (3d Cir. 2024) (emphasis in original).

The bar for *in camera* review is even lower than a *prima facie* case. Relator need only provide "a factual basis adequate to support a good faith belief by a reasonable person that *in camera* review of the materials may reveal evidence to establish the claim that the crime-fraud exception applies." *United States v. Zolin*, 491 U.S. 554, 572 (1989). As the Special Master

acknowledges, "The decision to engage in in camera review implicates a much more lenient standard of proof than the determination to apply the crime/fraud exception." (Order, at 11, *citing In re Neurontin Antitrust Litigation*, 801 F. Supp. 2d 304 (D.N.J. 2011) (cleaned up).)

II. Relator Has Provided an Adequate Factual Basis That Defendants Committed Fraud and the Challenged Communications Furthered the Fraud

A. Defendants Knew Their Representation to the Patent Office that Prednisone Coadministration Caused Zytiga's Commercial Success Was False, Because They Knew It Was an Important Competitive Weakness

It is important at the outset to emphasize that Relator is not just saying that counsel's communications *furthered* the fraud, but also that counsel's actions *constituted and implemented* the fraud, which is even worse. Defendants planned and implemented their fraudulent scheme in part through attorney-driven deliberation and filings with the Patent Office, in the FDA's Orange Book, and in patent litigation, [redacted]. Defendants represented to the Patent Office that prednisone coadministration was the reason for Zytiga's commercial success, but Defendants knew it was the central weakness. The facts and evidence that Relator presents in pages 4-11, *supra,* are themselves sufficient to establish an adequate factual basis of actionable fraud under the False Claims Act, which requires that Defendants either had actual knowledge that their statement was false, acted with deliberate indifference, or were reckless. 31 U.S.C. § 23729(b)(1).

The Special Master acknowledged that plenty of documents demonstrate Defendants knew and understood that prednisone coadministration was a "weakness" of Zytiga, but he dismissed this evidence based on Defendants' say-so by drawing a distinction between "the marketing of Zytiga" as a weakness, and the "therapeutic and clinical benefits of Zytiga (i.e., the strength and efficacy of the drug)." (Order, at 16) Relator submits this was error for four reasons.

First, the premise is wrong. The examples in pages 6-9 directly show Defendants' belief

regarding whether prednisone coadministration—namely, the invention in the '438 patent—was a "weakness" for Zytiga's commercial success, which undermines the required nexus. [redacted]

Second, the Special Master's disregard of Zytiga's "marketing" weaknesses misapprehends the role played by Defendants' marketing department, [redacted] Moreover, a marketing weakness

[7] The document also mentions that [redacted]." This, as well as the many other factors that were actually driving Zytiga's commercial success described on pages 7 and 9-11, *supra*, was not disclosed to the Patent Office, even though Defendants were obligated to disclose them.

is necessarily a competitive weakness. Zytiga may have been commercially successful, but the evidence shows it was *not* because of prednisone coadministration (as already concluded by the district court and PTAB) and further that Defendants did not *believe* it was because of prednisone coadministration. Yet, that is not what the Defendants told the Patent Office. Instead, they intentionally represented there was a nexus between the invention claimed in the '438 patent (prednisone coadministration) and Zytiga's sales.

Third, the Special Master's decision accepts Defendants' alibis concerning their supposed belief in the efficacy advantage provided by prednisone coadministration (which is not only false and baseless, but which also appears to be a *post hac* rationalization concocted by Defendants' attorneys) over Relator's evidence. The Special Master's resolution of this factual dispute in favor of Defendants is inconsistent with how the courts should assess the application of the crime-fraud doctrine, which requires Relator only to provide a factual basis sufficient to support a *good faith belief* by a *reasonable person* that *in camera* review of the materials *may* reveal evidence to establish the claim that the crime-fraud exception applies. The Special Master erred in setting the bar far too high—indeed, the requisite factual basis is a much more lenient standard than even a *prima facie* showing of fraud.

Fourth, the Special Master's acceptance of Defendants' argument is foreclosed by the prior decisions rejecting Defendants' commercial success argument for Zytiga based on efficacy. *Amerigen*, 2018 WL 454509, at *18 ("Zytiga's anti-cancer effects come from abiraterone acetate" and not from prednisone coadministration); *see also BTG Int'l Ltd.*, 923 F.3d 1063, 1076 (Fed. Cir. 2019); *Mylan*, 2018 WL 456305, at *18; *Wockhardt*, 2018 WL 456328, at *21; *BTG*, 352 F. Supp. 3d at 386. In their opposition papers, Defendants tried to relitigate this issue after having it rejected repeatedly, and it was error for the Special Master to credit Defendants' rejected

explanation as a basis for disregarding Relator's factual basis for *in camera* review. Indeed, Defendants argued in the patent infringement action that prednisone coadministration increased Zytiga's efficacy and anti-tumor properties. *See BTG Int'l Ltd. v. Amneal Pharma. LLC*, Case No. 2:15-cv-05909-KM-ESK (D.N.J.) (ECF 552, at 2). The generic competitors debunked Defendants' arguments. *Id.,* at 3-7. The PTAB also rejected Defendants' argument. *Amerigen*, 2018 WL 454509, at *17.

The Special Master therefore erred in concluding that "Relator's disagreement with the merits of Defendants' commercial success arguments" cannot support *in camera* review. (Order, at 16.) There can be no disagreement over the *merits* of Defendants' commercial success argument. The only open question is one of scienter, and that's a fact issue for which Relator has presented a more than adequate factual basis to support a good faith belief, by a reasonable person, that *in camera* review may reveal relevant evidence. The Special Master should not have resolved that factual issue for Defendants. The evidence establishes a sufficient factual basis for a reasonable person to believe that Defendants' highest-level executives and patent counsel *knew* (or at least were reckless or deliberately ignorant) that prednisone coadministration was not the reason for Zytiga's commercial success (and in fact was one of primary weaknesses), and they failed to disclose what they actually believed to have been the real reasons for it.

B. Defendants' Long Range Financial Projections Provides Further Evidence of Fraud

The Special Master determined that Defendants' [redacted] does not establish that Defendants knew or believed that the '438 Patent was obtained by fraud, even if it could be "evidence" of it. (Order, at 17-18.) But the relevant question is whether Relator's evidence establishes a factual basis sufficient for a reasonable person to form a good faith belief as to

Defendants' scienter. Relator has certainly done so with respect to the fact that prednisone coadministration was known as a "weakness" by Defendants' top executives. In addition to that, the evidence described on pages 13-16 and 18 concerning [redacted] also demonstrate scienter. If Defendants' internal projections all assumed [redacted] that is a sufficient basis for a reasonable person to believe that Defendants knew the patent would be invalidated. A reasonable inference can be made that Defendants were just banking on the intervening delay to squeeze as much monopoly profits before it did. It was error for the Special Master to resolve this factual issue in favor of Defendants' alternative explanation, instead of focusing on whether Relator has established a factual basis to support a good faith belief by a reasonable person justifying *in camera* review.

A practical reason why the Special Master should not have resolved factual disputes in favor of Defendants is demonstrated by the fact that Relator would readily be able to provide numerous additional pieces of evidence undermining Defendants' assertions. For example, in a July 23, 2024 deposition that occurred after briefing on Relator's original motion was submitted, Defendants' Director of Marketing testified that [redacted] These dates are significant: as it turns out, the PTAB invalidated the '438 Patent in January 2018, *see Amerigen*, 2018 WL 454509, at *18 (January 17, 2018); *Mylan*, 2018 WL 456305, at *18 (January 17, 2018); *Wockhardt*, 2018 WL 456328, at *21 (January 17, 2018). This Court issued its decision against Defendants and in favor of the generic companies in October 2018. 352 F. Supp. 3d at 386

(October 31, 2018). Defendants therefore were *very* accurate in predicting when they would lose their lawsuits, and the effects such loss would have. (*See also* Ex. 34, [redacted]

[redacted]

C. Defendants' Wrongful Listing of the '438 Patent in the Orange Book and Subsequent Assertion of the Patent Against Generics Provide Additional Facts Supporting a Good Faith Belief Warranting In Camera Review

Relator provides on pages 4 through 18 above ample factual bases for a reasonable person to believe, in good faith, that Defendants wrongfully listed the '438 Patent in the Orange Book to trigger a regulatory delay and exclude generic competitors, even though they knew that the patent was fraudulent and invalid. These allegations are important, because Relator contends that between July 2013 and September 2014, Defendants allowed the '438 Patent to issue, and listed it in the Orange Book, despite lacking a good faith belief that it would survive a validity challenge. Any assessments by counsel, any advice given, or any actions taken by counsel in listing the '438 Patent in the Orange Book falls within the crime-fraud exception. *See Abbott*, 96 F.4th at 377-78.

The Special Master determined that Relator's "reliance on J&J having listed the '438 Patent in the Orange Book and having commenced patent infringement litigation to enforce the '438 Patent unavailing." (Order, at 16.) The Special Master arrived at this conclusion by mistakenly assuming that these events "fall outside the claims" alleged in the Complaint. (*Ibid.*) To the contrary, the Complaint describes in detail how Defendants effectuated their fraud by listing the '438 Patent in the Orange Book to trigger a 30-month regulatory stay and as a predicate to commence litigation against competitors to keep them out of the market. (SAC, ¶¶ 40-42, 48-51, 58, 96-98.) As an integral part of the fraudulent scheme, Defendants listed the '438 Patent in the Orange Book even though they knew it could not be "reasonably asserted" against generic competitors (because they obtained it through fraud). Defendants did so to force generic competitors to file Paragraph IV certifications, thereby triggering a regulatory 30-month stay

during which the FDA could not approve any generic competitor to market a lower-priced alternative. (SAC ¶¶ 40-42, 48-51, 58, 92, 96-98, 119.) In the Court's decision denying Defendants' motion to dismiss, Judge McNulty described in detail the Complaint's allegations about how Defendants' improper listing of the '438 Patent in the Orange Book played an integral part of Defendants' fraudulent scheme. As this Court explained, "Plaintiff alleges that the '438 Patent's publication in the Orange Book allowed Defendants to delay generic entry into the market . . . [which] forced these generic manufacturers to file Paragraph IV certifications, allowing Defendants to file patent infringement lawsuits . . . and to trigger a 30-month stay of FDA approval of the generics." *Janssen*, 576 F. Supp. 3d at 221 (citing SAC ¶¶ 58, 93-96, 98-100, 105).

The Special Master also found that the improper listing of the '438 Patent in the Orange Book, and the subsequent assertion of the patent in patent litigation to exclude competitors, are too "attenuated" and lack sufficient connection to Defendants' misuse of attorney advice and communications sufficient for *in camera* review. (Order, at 16-17.) But there clearly is a "logical link" between Defendants' misconduct and the Government's damages. In fact, the Orange Book listing and subsequent litigation were *intended* to effectuate Defendants' fraud. Obtaining a fraudulent patent does nothing unless you wield it against competitors to exclude them from the market. The way that Defendants schemed to do that was listing the patent in the Orange Book; this is precisely what the Complaint alleges, and what Judge McNulty described in his decision.

Finally, the Special Master believed that Judge McNulty "rejected" Relator's theories in the prior litigation by finding that certain antitrust class plaintiffs did not adequately plead that Defendants' patent infringement litigation against generic competitors was "not objectively baseless." (Order, at 16, *citing La. Health Serv. & Indemnity Co. v. Janssen Biotech, Inc.*, No. 19-14146, 2021 WL 4988523, at *8 (D.N.J. Oct. 27, 2021).) This is incorrect. Judge McNulty

dismissed the antitrust plaintiffs' complaint because plaintiffs did not allege a theory of fraud on the Patent Office, which Judge McNulty pointedly noted when he observed that the antitrust plaintiffs were "walking a tightrope" by not alleging "fraud on the PTO" like Relator did. *La. Health Serv.*, 2021 WL 4988523, at *8 n.21. This is materially different than what the Court decided in *this* case, based on Relator's well-pleaded allegations of patent fraud.[8] Even though this case was coordinated with the antitrust action, and the dockets consolidated, Judge McNulty went out of his way to write a separate decision upholding Relator's claims in this case, demonstrating that his prior observations about a "close call" in *Louisiana Health Services* do not apply here, which is grounded on well-pleaded allegations based on patent fraud, not sham litigation. This case is based on a different theory with a different standard of proof than what was pursued in the antitrust cases.

D. Relator Has Made a Factual Showing Adequate to Support a Good Faith Belief By a Reasonable Person that the Challenged Communications Were Made in Furtherance of the Fraud

The Special Master determined that, while the LRFPs may be "evidence" of fraud, they do not establish that Defendants' in-house attorneys' communications were made in *furtherance* of the fraud. (Order, at 17-18) Yet, the detailed evidence presented on pages 1-18, *supra*, does precisely that. Relator's evidence establishes a factual basis supporting a good faith belief that Defendants *planned and implemented* their fraudulent scheme through attorney-driven deliberation and regulatory and legal filings, as well as through financial modeling based on

[8] Defendants say that during the patent infringement trial, the Court grappled with numerous complicated issues that were close calls, so that their assertion of the patent could not have been frivolous. Defendants, however, raised several theories of validity that the patent examiner did not find persuasive, such as unexpected results, skepticism, failure of others, and threshold issues relating to obviousness. Resolving those issues may have been close calls, but none of those issues are relevant here. *See BTG Int'l Ltd.*, 923 F.3d at 1076 (Fed. Cir. 2019). The patent examiner granted Defendants' application for a single reason: commercial success.

attorney-calculated LOE assumptions.

In *In re Abbott Labs.*, 96 F.4th 371 (3d Cir. 2024), the complaint alleged that Abbott unlawfully protected its monopoly on one of its drugs by asserting a patent against generic competitors in sham litigation for the purpose of delaying generic entry. The plaintiffs filed a motion for *in camera* review of certain communications of Abbott's in-house attorneys "concerning whether to file" the sham litigation against generic competitors because "such communication would not be protected by the attorney-client privilege due to the crime-fraud exception." *Id.* at 377. The district court reviewed and ordered production of certain documents, and the Third Circuit affirmed, crediting the district court's holding that "it is reasonable to infer from their legal research and analysis that the attorneys knew the filing of the litigation would be a sham" because in-house counsel were the "key decisionmakers who directed the filing of sham litigation" and thus "used their own legal research and analysis—the documents at issue here—in furtherance of fraud." *Id.* at 378 (cleaned up). The Court explained that "the lawsuit's baselessness, combined with the client's subjective intent to interfere with administrative and judicial procedures associated with patent rights . . . trigger[ed] the crime-fraud exception." *Id.* at 382.

The Third Circuit thus recognized the applicability of the crime-fraud exception to a case such as this, where in-house patent counsel decide to assert a fraudulently obtained patent to delay generic entry. In this type of situation, in-house attorneys do not just render legal advice; they serve as key decisionmakers that act in furtherance of fraud by implementing the unlawful scheme. This makes *in camera* review to determine the applicability of the crime-fraud exception particularly appropriate once a factual basis for a good faith belief that such review may reveal crime-fraud evidence has been established. The Special Master distinguished *Abbott*, saying that the Third Circuit's decision was premised in part on the finding that the underlying lawsuit was

"baseless" and that no such finding has been made here. But that distinction is without difference here. *Abbott* involved an affirmative claim based on sham litigation—which has stringent standards that the litigation be objectively unreasonable. *Id.* at 380. If those requirements are met, the defendant could be liable regardless of whether the patent itself was fraudulently obtained, or even invalid. Here, Relator does not rely on a freestanding claim of sham litigation. Rather, Relator alleges that Defendants' listing of the patent in the Orange Book and subsequent assertion of the '438 Patent in litigation *effectuated* the fraudulent scheme, which was started when Defendants obtained the '438 Patent through fraud. There is no requirement that such litigation itself must be objectively baseless, as would be required for a standalone sham litigation theory. Indeed, proving scienter under the False Claims Act does not require showing that the defendant's claims or statements were objectively baseless. *See United States ex rel. Schutte v. SuperValu Inc.*, 589 U.S. 739, 749 (2023) ("The FCA's scienter element refers to [defendants'] knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed.").[9]

Finally, the Special Master believed that *In re Neurontin*, 801 F. Supp. 2d 304, is directly applicable (Order, at 13-15), but that case is quite different. In *Neurontin*, there was no logical link between the challenged patent litigation and the crime supposedly serving as the basis for applying the crime-fraud exception, *i.e.*, off-label marketing. They are simply two different types of misconduct. That is not the case here, where the challenged communications, like in *Abbott,* involved in-house counsel's research and analysis to further the fraud *at issue*.

[9] The Special Master also misapprehended Relator's argument, because the Order assumes that Relator's arguments for *in camera review* are premised on Defendants' "assertion of frivolous legal claims." (Order, at 18.) Although Relator does contend that Defendants' assertion of the patent in litigation helped *effectuate* the fraud (regardless of whether it would have been otherwise frivolous or objectively baseless as required by a sham litigation cause of action), Relator's Motion is based on events from the Notice of Allowance on July 3, 2013, to the listing of the patent in the Orange Book on September 30, 2014. The patent was not asserted in patent litigation until later, and Relator is not seeking *in camera* review of those communications at this time.

III. The Number of Documents Sought for Initial Review is Reasonable

The Special Master declined to conduct an *in camera* review because Relator's request of 200 documents is "somewhat broad," and he did not believe that Relator provided a rationale as to why or how those documents were selected. Defendants have withheld the contents of those documents, so Relator inherently must make a judgment call as to which documents to select. Nevertheless, Relator's rationale is sound. He has chosen a narrow period from July 3, 2013 (when Defendants received the first Notice of Allowance) to September 30, 2014 (when Defendants listed the '438 Patent in the Orange Book). This time is a particularly target-rich environment. Nonetheless, Relator narrowed his request to a targeted list of 200 documents, and he has identified and highlighted 50 of those documents for priority review. In doing so, Relator has used the available circumstantial evidence—such as the time period of particular communications, the parties to those communications, the proximity of those communications to key events, and the nature of the descriptions in the privilege logs—to identify documents that seem most likely to reveal actions by counsel in furtherance of the fraudulent scheme. *See* pages 4 and 11-18, above.

If the Court believes 200 documents is too many, then Relator suggests that instead of denying Relator's Motion outright, the Court could begin with the 50 highlighted documents, or direct Relator to further narrow his request to an even smaller number of documents.

CONCLUSION

For the foregoing reasons, Relator respectfully requests that the Court require Defendants to provide for *in camera* review the documents identified in Exhibit 30. If crime-fraud communications are found, Relator respectfully requests that the Court order the parties to negotiate a protocol for reviewing the remaining documents from the target time period set forth in Exhibit 1. Relator respectfully requests oral argument.

LITE DEPALMA GREENBERG & AFANADOR, LLC

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/s/ Bruce D. Greenberg
Bruce D. Greenberg
570 Broad St, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
bgreenberg@litedepalma.com

HERRERA KENNEDY LLP
Nicomedes Sy Herrera (*pro hac vice*)
Bret D. Hembd (*pro hac vice*)
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
NHerrera@HerreraKennedy.com
BHembd@HerreraKennedy.com

SPARACINO PLLC
Tejinder Singh (*pro hac vice*)
1920 L Street, NW, Suite 835
Washington, DC 20036
Telephone: (202) 629-3530
tejinder.singh@sparacinopllc.com

MORGAN & MORGAN
James Young (*pro hac vice*)
501 Riverside Ave, Suite 1200
Jacksonville, FL 32202
Telephone: (904) 361-0012
JYoung@ForThePeople.com

MORGAN & MORGAN
Clark Bolton (*pro hac vice*)
Juan Martinez (*pro hac vice*)
201 N Franklin Street, 7th Floor
Tampa, FL 33602
Telephone: (813) 223-5505
CBolton@ForThePeople.com
JuanMartinez@ForThePeople.com

Attorneys for Plaintiff-Relator Zachary Silbersher